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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Converge Acetabular System.

Manufacturer:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	August 15, 2001
Contact Person:	Mitchell A. Dhority Director, Regulatory & Clinical Affairs
Classification Name:	Hip Joint Metal/Polymer/Metal Semi-constrained Porous-coated Uncemented Prosthesis, 21CFR 888.3358
Common/Usual Name:	Acetabular Shell Components
Trade/Proprietary Name:	Sulzer Orthopedics Converge Acetabular System

PRODUCT DESCRIPTION

The Converge Acetabular System consists of four modular shell options which mate with currently marketed insert components for replacement of the acetabulum during total hip arthroplasty. They are designed to provide congruency with the ability to effectively seal the acetabulum, and may be implanted with or without bone cement.

I. Common Features

The following design features are common to the four metallic shells of the Converge Acetabular System family:

- Substrate Material – All of the Converge shells are manufactured from titanium alloy (Ti-6Al-4V ELI, ASTM F136)

- Porous Coating – Cancellous Structured Titanium (CSTi) porous coating (commercially pure titanium, ASTM F1580) covers the entire outer surface of the Converge shells, with the exception of regions adjacent to the dome hole and screw holes, and a small band around the opening of the shell. The porous coating allows for biological fixation to occur.

- Shell/Insert Locking Mechanism – Because all four shells of the Converge System share the same internal locking mechanism, they can be used with the currently marketed Sulzer Orthopedics Inter-Op Acetabular inserts (standard polyethylene, Durasul and Metasul).

- Threaded Dome Hole/Dome Hole Plug – Another feature common to all four shells of the Converge family is a threaded dome hole. During implantation of the shell, an impactor/alignment instrument with mating threads is inserted into the dome hole to place the shell into the acetabulum. Once the shell has been inserted and the impactor/alignment tool is removed, the dome hole provides visual access to the acetabulum so that the surgeon can ensure complete seating of the device. Once adequate seating of the device into the acetabulum has been assured, the threaded titanium dome hole plug (ASTM F67) can be screwed into place to prevent unwanted material migration through the dome hole. Once in place, the plug is recessed within the dome hole and does not protrude beyond the outer diameter of the shell.

II. Shell Options

The following is a description of product-specific features for each of the shell components of the Converge product family:

A. Converge Cluster-Hole Porous Shell with Sealed Screw Holes

The Converge Cluster-Hole shell is a hemispherically shaped acetabular shell that features screw holes sealed with plugs that are sintered into place. The plugs may be removed during surgery, if desired, to allow for supplemental fixation with bone screws.

The cluster-hole shell features superior holes in order to increase fixation options. Shells with an outside diameter ranging from 39mm to 47mm have a two-hole configuration. Shells ranging from 49mm to 71mm have a pattern of three holes. Sizes are reflective of the outer shell diameter and are available in 2mm increments.

When left in place, the screw hole plugs limit the potential for fibrous tissue growth (for cementless application) or cement extrusion (in cemented application) into the shell. The plugs also act to restrict debris from migrating through the acetabular shell holes into the acetabulum.

If the surgeon opts to provide additional fixation of the device, the shell's screw holes will accommodate bone screw attachment to the ilium. Removal of the sintered plugs is accomplished with the use of a specially designed removal tool.

B. Converge Rim Flare Porous Shell with Spikes and Sealed Screw Holes

The Rim Flare acetabular shell is designed to facilitate load transfer, limit the potential for tilting or rotation of the device upon implantation, and give surgeons flexibility in press-fitting the shell to the best available bone stock. The component features an offset radius in its rim region that permits loads to be transmitted to the periphery of the outer shell surface. The enhanced offset radius also facilitates an

initial press-fit of the shell into the acetabulum.

The outer surface of the shell has three dome spikes that are press-fit into the cancellous bone of the reamed acetabulum in order to minimize the potential for tilting or rotation of the device. Similar to the Cluster-Hole Shell, the Rim Flare features two sintered screw hole covers in dome that may be left in place (if screw fixation is not desired) or removed (for supplemental screw fixation).

The Rim Flare shell will be offered in outer diameters ranging from 39-71mm (in 2mm increments).

C. Converge Multi-Hole Porous Shell with Sealable Screw Holes

The Converge Multi-Hole Porous Shell with Sealable Screw Holes is a hemispherical shell designed to expand the surgeon's options for treatment of scenarios where acetabular bone stock is deficient (e.g., revision cases).

The Multi-Hole Porous Shell features five to nine screw holes (depending on shell size), to allow for screw placement into the ilium, ischium, and pubis. Three to five of the screw holes are located at the ilium, which normally provides more bone stock for attachment. There are one to two screw holes each in the ischium and pubis regions.

Screw holes that are not used in attaching the shell to the acetabulum can be plugged in order to limit the potential for fibrous tissue growth into the shell (for cementless application) or cement extrusion into the shell. A secondary benefit of the plugs in both applications is their ability to restrict debris from migrating through the acetabular shell holes into the acetabulum. The plugs may be manufactured from either Ti-6Al-4V (ASTM F136) or unalloyed titanium (ASTM F67).

The Converge Multi-Hole Porous Shell with Sealable Screw Holes is available in outer diameters ranging from 43mm to 81mm, in 2mm increments.

D. Converge Protrusio Porous Shell with Sealable Screw Holes

The Converge Protrusio Shell is designed to provide the surgeon with a shell option that addresses the need to accommodate a deeper acetabular socket caused by protrusio defects. The outer shell geometry features a gradual buildup of material from the shell's rim to its dome, thus allowing it to attain the fit and fill of the deeper acetabulum. This design also gives the surgeon the ability to re-create the anatomical hip center as closely as possible while avoiding medialization of the femoral component, to compensate for protrusio defects where there has been a thinning of the medial and superior walls of the acetabulum.

Like the Multi-Hole shell, the Protrusio features five to nine screw holes (depending on shell size) to allow for screw placement into the ilium, ischium, and pubis. The screw hole plugs used with the Multi-hole Shell may also be used with the Protrusio Shell.

The device is available in external shell diameters ranging from 53mm to 81mm, in 2mm increments.

SPECIFIC DIAGNOSTIC INDICATIONS

Components of the Converge Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed arthroplasty.

SUBSTANTIAL EQUIVALENCE

The Converge Acetabular System is similar to the following commercially available devices in terms of materials, general design features, and intended uses:

- Sulzer Orthopedics Inter-Op Acetabular System
- Zimmer Trilogy Acetabular System
- Stryker/Osteonics/Howmedica System 12 Acetabular System
- Smith & Nephew Orthopaedics Reflection Acetabular System
- DePuy Duraloc Acetabular System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Mr. Mitchell A. Dhority
Director, Regulatory and Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K012739
Trade/Device Name: Converge Acetabular System
Regulation Number: 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: August 15, 2001
Received: August 16, 2001

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 4 2001

510(k) Number (if known): K012739

Device Name: Converge Acetabular System

Indications for Use:

Components of the Converge Acetabular System are intended for use in total hip arthroplasty for treatment of the following:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use**

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Res[illegible]tive
and Neurological Devic[illegible]

510(k) Number K012739